120.430: THERAPEUTIC RADIATION MACHINES

120.431: Purpose and Scope

(A) 105 CMR 120.430 establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of 105 CMR 120.430 are in addition to, and not in substitution for, other applicable provisions of these regulations.

(B) The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by 120.433(C).

120.432: Definitions

As used in 105 CMR 120.430, the following definitions apply:

Absorbed Dose (D) means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

Absorbed Dose Rate means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible Surface means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

Added Filtration means any filtration which is in addition to the inherent filtration.

Air Kerma (K) means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

Barrier (See "Protective barrier" in 105 CMR 120.005).

Beam Axis means the axis of rotation of the beam limiting device.

Beam-limiting Device means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

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Beam Monitoring System means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Beam Scattering Foil means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Bent Beam Linear Accelerator means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Certified Health Physicist means and individual certified by the American Board of Health Physics as a health physicist.

Changeable Filters means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

Contact Therapy System means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters.

Detector (See "Radiation Detector" in 105 CMR 120.402).

Dose Monitor Unit (DMU) means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

Dosimetry System means a device which can measure radiation dose.

External Beam Radiation Therapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening Filter means a filter used to flatten the absorbed dose rate over the radiation field.

Filter means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 105 CMR 120.436.

Gantry means that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

Gray (Gy) means the SI unit of absorbed dose, kerma, and specific energy imparted equal to one joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. [1 Gy=100 rad].

Interlock means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Interruption of Irradiation means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Isocenter means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

Leakage Radiation means radiation emanating from the radiation therapy system except for the useful beam.

Light Field means the area illuminated by light, simulating the radiation field.

mA means milliampere.

Megavolt (MV) [mega electron volt (MeV)] means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note: current convention is to use MV for photons and MeV for electrons.]

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Monitor Unit (MU) (See "Dose Monitor Unit").

Moving Beam Radiation Therapy means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

Nominal Treatment Distance means:

(a) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

(b) For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

Peak Tube Potential means the maximum value of the potential difference across the X-ray tube during an exposure.

Periodic Quality Assurance Check means a procedure which is performed to ensure that a previous calibration continues to be valid.

Prescribed dose, means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

Primary Dose Monitoring System means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

Primary Protective Barrier (See "Protective Barrier" in 105 CMR 120.005).

Radiation Field (See Useful Beam)

Radiation Head means the structure from which the useful beam emerges.

Radiation Therapy Physicist means an individual qualified in accordance with 105 CMR 120.433(D).

Redundant Beam Monitoring System means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

Secondary Dose Monitoring System means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Secondary Protective Barrier (See "Protective Barrier" in 105 CMR 120.005).

Source means the region and/or material from which the radiation emanates.

Source-skin Distance (SSD) [See Target-skin Distance]

Stationary Beam Radiation Therapy means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray Radiation means the sum of leakage and scattered radiation.

Target means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

Target-skin Distance (TSD) means the distance measured along the beam axis from the target to the surface of the irradiated object or patient.

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Tenth-value Layer (TVL) means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

Termination of Irradiation means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Therapeutic Radiation Machine means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

Tube means an X-ray tube, unless otherwise specified.

Tube Housing Assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Useful Beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

Virtual Source means a point from which radiation appears to originate.

Wedge Filter means a filter which effects continuous change in transmission over all or a part of the useful beam.

Written directive means an order in writing for the administration of radiation to a specific patient or human research subject, as specified in 105 CMR 120.435(A).

X-ray Tube means any electron tube which is designed to be used primarily for the production of X-rays.

120.433: General Administrative Requirements for Facilities Using Therapeutic Radiation Machines

(A) Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of 105 CMR 120.430 are met in the operation of the therapeutic radiation machine(s).

(B) Prohibition A therapeutic radiation machine which does not meet the provisions of 105 CMR 120.000 shall not be used for irradiation of patients.

(C) Training for External Beam Radiation Therapy Authorized Users The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall require the authorized user to be a physician who:

(1) Is certified in:

(a) Radiology or therapeutic radiology by the American Board of Radiology; or,

(b) Radiation oncology by the American Osteopathic Board of Radiology; or,

(c) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or,

(d) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or,

(2) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation

techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(a) To satisfy the requirement for instruction in 105 CMR 120.433(C)(2), the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of ionization radiation; and
4. Radiation biology.

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(b) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

1. Review of the full calibration measurements and periodic quality assurance checks;
2. Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
3. Using administrative controls to prevent misadministrations;
4. Implementing emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and,
5. Checking and using radiation survey meters.

(c) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional year years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/ contraindications;
2. Selecting proper dose and how it is to be administered;
3. Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and,
4. Post-administration follow-up and review of case histories.

(d) Notwithstanding the requirements of 105 CMR 120.433(C)(1) and 120.433(C)(2), the registrant for any therapeutic radiation machine subject to 105 CMR 120.436 may also submit the training of the prospective authorized user physician for Agency review on a case-by-case basis.

(e) A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.

~~(3) The requirements of 105 CMR 120.433(C)(1) must be met within 24 months after July 9, 1999.~~

(D) Training for Authorized Medical Physicist for Radiation Therapy ~~Physicist~~ The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall require the Radiation Therapy Physicist to:

(1) Be registered with the Agency, under the provisions of 105 CMR 120.026, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and,

(2) Be certified by the American Board of Radiology in:

(a) Therapeutic radiological physics; or

(b) Roentgen-ray and gamma-ray physics; or

(c) X-ray and radium physics; or

(d) Radiological physics; or,

(3) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or,

(4) Be certified by the Canadian College of Medical Physics; or,

(5)(a) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 105 CMR 120.434(A), 105 CMR 120.436(P)/(T), and 105 CMR 120.436(Q)(U) under the supervision of a Radiation Therapy Physicist during the year of work experience~~.~~; and,

(b) Has obtained written certification, signed by a preceptor authorized medical physicist, that the individual has

satisfactorily completed the requirements in 120.433(D)(5)(a) and has achieved a level of competency sufficient to independently function as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

~~(6) Notwithstanding the provisions of 105 CMR 120.433(D)(5), certification pursuant 105 CMR 120.433(D)(2), (D)(3), and/or (D)(4) shall be required on or before one year after July 91, 1999 for all persons currently qualifying as a Radiation Therapy Physicist pursuant to 105 CMR 120.433(D)(5).~~

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(E) Qualifications of Operators.

(1) Individuals who will be operating a therapeutic radiation machine for medical use shall possess a valid Massachusetts License as a Radiologic Technologists in Radiation Therapy.

(2) The names and the respective training records of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least two years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(F) Written safety procedures and rules shall be developed by a Radiation Therapy Physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(G) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by an authorized user meeting the requirements of 105 CMR 120.433(C) who is specifically identified on the Certificate of Registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

(H) Visiting Authorized User. Notwithstanding the provisions of 105 CMR 120.433(G), a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's Certificate of Registration for up to 60 days per calendar year under the following conditions:

(1) The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee; and

(2) The visiting authorized user meets the requirements established for authorized user(s) in 105 CMR 120.433(C)(1) and (C)(2); and

(3) The registrant maintains copies of all records specified by 105 CMR 120.433(H) for five years from the date of the last visit.

(I) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of 105 CMR 120.430, these individuals are also subject to the requirements of 105 CMR 120.201, 120.205 and 120.502.

(J) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

(1) Report of acceptance testing;

(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 105 CMR 120.430, as well as the name(s) of person(s) who performed such activities;

(3) Records of maintenance and/or modifications performed on the therapeutic radiation machine after July 9, 1999, as well as the name(s) of person(s) who performed such services;

(4) Signature of the Radiation therapy Physicist or Authorized User authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(K) Records Retention. All records required by 105 CMR 120.430 shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in 105 CMR 120.430. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

120.434 General Technical Requirements for Facilities Using Therapeutic Radiation Machines

(A) Protection Surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with 105 CMR 120.438. The radiation protection survey shall be performed by, or under the direction of, a Radiation Therapy Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation. The following standards must be met and recorded:

(a) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 105 CMR 120.211(A); and,

(b) Radiation levels in unrestricted areas do not exceed the limits specified in 105 CMR 120.221(A) and 120.221(B).

(2) In addition to the requirements of 105 CMR 120.434(A)(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

(a) After making any structural or composite modifications to the treatment room shielding;

(b) After making any changes in the location of the therapeutic radiation machine within the treatment room;

(c) After relocating the therapeutic radiation machine; or,

(d) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the Radiation Therapy Physicist or a Certified Health Physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey;

(4) If the results of the surveys required by 105 CMR 120.434(A)(1) or 120.434(A)(2) indicate any radiation levels in excess of the respective limit specified in 105 CMR 120.434(A)(1), the registrant shall lock the control in the "OFF" position and not use the unit:

(a) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or,

(b) Until the registrant has received a specific exemption from the Agency.

(B) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by 105 CMR 120.434(A) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 105 CMR 120.221(A) and 120.221(B), before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 105 CMR 120.221(A) and 120.221(B);

(2) Perform the survey required by 105 CMR 120.434(A) again; and,

(3) Include in the report required by 105 CMR 120.434(D) the results of the initial survey, a description of the modification made to comply with 105 CMR 120.434(B)(1), and the results of the second survey; or,

(4) Request and receive a registration amendment under 105 CMR 120.221(C). that authorizes radiation levels in unrestricted areas greater than those permitted by 105 CMR 120.221(A) and 120.221(B).

(C) Dosimetry Equipment.

(1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine

(AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

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(a) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(b) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 105 CMR 120.434(C)(1) This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 105 CMR 120.434(C)(1);

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 105 CMR 120.434(C)(1) and (C)(2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a Radiation Therapy Physicist.

(D) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for any therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall furnish a copy of the records required in 105 CMR 120.434(A) and 120.434(B) to the Agency within 30 days following completion of the action that initiated the record requirement.

120.435: Written Directives ~~Quality Management Program~~

~~[Note: For purposes of 105 CMR 120.435 the Quality Management Program for therapeutic radiation machine facilities are the same as for teletherapy. In addition, the word registrant as used in 105 CMR120.400 is to be substituted for the word licensee as used in 105CMR120.500 and the word registration for license in applying the referenced provisions listed below.]~~

(A) A written directive, as defined in 105 CMR 120.432, must be dated and signed by an authorized user prior to the administration of radiation.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(B) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(C)(1) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

If because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The registrant shall retain a copy of the written directive for three years.

(D) Procedures for Administrations of Doses of Radiation

The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

(1) Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

(a) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and,

(b) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and,

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

(E) Reports and Notification of Medical events

(1) Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose:

(a) Involves the wrong patient, wrong treatment modality, or wrong treatment site; or

(b) Consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(c) The calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(d) The calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

(2) A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

(3) The registrant shall notify the Agency by telephone no later than the next calendar day after discovery of the medical event.

(4) The registrant shall submit a written report to the Agency within 15 days after discovery of the medical event.

(a) The written report must include:

1. The registrant's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

5. The effect, if any, on the individual(s) who received the administration;

6. Actions, if any, that have been taken, or are planned, to prevent recurrence;

7. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The registrant shall provide notification of the medical event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall retain a record of a medical event in accordance with 105 CMR 120.435(E). A copy of the record required under 105 CMR 120.435(E) shall be provided to the referring physician if other than the registrant, within 15 days after discovery of the medical event.

(E) Records of Medical Events

A registrant shall retain a record of medical events reported in accordance with 105 CMR 120.435(E) for three years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the medical event; medical event a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the registrant notified the individual (or the individual's responsible relative or

guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

~~(1) Prescribed dose means see 105 CMR 120.502: Prescribed Dose(2).~~
~~(2) Misadministration means see 105 CMR 120.502: Misadministration(4).~~
~~(3) Recordable Event means see 105 CMR 120.502: Recordable Event(5).~~
~~(4) Written Directive means see 105 CMR 120.502: Written Directive(4).~~

~~(B) Scope and Applicability. See 105 CMR 120.513: Quality Management Program.~~

~~(C) Records, Notifications, and Reports of Misadministration see 105 CMR 120.514: Records, Notifications, and Reports of Misadministration.~~

120.437: Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)

(A) Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 105 CMR 120.437 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 :Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 105 CMR 120.438.

(B) Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(1) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (*i.e.* patient plane), shall not exceed a maximum of 0.2% and an average of 0.1% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

(2) Except for the area defined in 105 CMR 120.437(B)(1), the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5% of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

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(3) For equipment manufactured after July 9, 1999, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 105 CMR 120.437(B)(1) through (B)(3) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

(C) Leakage Radiation Through Beam Limiting Devices.

(1) Photon Radiation. The secondary collimators shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2% (averaged over a one cm squared area) of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeters by ten centimeters radiation field;

(2) Electron Radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(a) A maximum of 2% and average of 0.5% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(b) A maximum of 10% of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of Leakage Radiation.

(a) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;

(b) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

(D) Filters/Wedges.

(1) Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

(2) If the absorbed dose rate information required by 105 CMR 120.437(I) relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

(3) For equipment manufactured after the effective date of these regulations which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

(a) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

(b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(c) A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

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(d) An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

(E) X-Ray/Neutron Contamination of the Useful Beam. For equipment manufactured after the effective date of these regulations, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

(F) Beam Monitors. All therapeutic radiation machines subject to 105 CMR 120.437 shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(1) Equipment manufactured after the effective date of these regulations shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

(2) Equipment manufactured on or before the effective date of these regulations shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;

(3) The detector and the system into which that detector is incorporated shall meet the following requirements:

(a) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

(b) Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

(c) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

(d) For equipment manufactured after the effective date of these regulations, the design of the beam monitoring systems shall ensure that the:

1. Malfunctioning of one system shall not affect the correct functioning of the other system(s); and
2. Failure of either system shall terminate irradiation or prevent the initiation of radiation.

(e) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these regulations, each display shall:

1. Maintain a reading until intentionally reset;
2. Have only one scale and no electrical or mechanical scale multiplying factors;
3. Utilize a design such that increasing dose is displayed by increasing numbers; and
4. In the event of power failure, the beam monitoring information required in 105 CMR 120.437(F)(3)(e)3. displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

(G) Beam Symmetry.

(1) A ~~B~~ bent-beam linear accelerator~~s~~ with beam flattening filter(s) subject to 105 CMR 120.437 shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in 105 CMR 120.437(G)(1) shall be able to detect field asymmetry greater than 10%; and

(3) The device(s) referenced in 105 CMR 120.437(G)(1) shall be configured to terminate irradiation if the specifications in 105 CMR 120.437(G)(2) can not be maintained.

(H) Selection and Display of Dose Monitor Units.

(1) Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

(2) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

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(3) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(4) For equipment manufactured after the effective date of these regulations, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

(I) Air Kerma Rate/Absorbed Dose Rate. For equipment manufactured after the effective date of these regulations, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. [The radiation detectors specified in 105 CMR 120.437(F) may form part of this system.] In addition:

(1) The dose monitor unit rate shall be displayed at the treatment control panel;

(2) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(3) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 105 CMR 120.437(I)(2) and (I)(3) for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Agency.

(J) Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.

(1) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

(2) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15% or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

(3) For equipment manufactured after July 9, 1999, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(K) Termination of Irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(L) Interruption of Irradiation. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(M) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

(1) A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

(2) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

(3) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

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(N) Selection of Radiation Type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

(2) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation modality which has been selected;

(4) An interlock system shall be provided to prevent irradiation with X-rays, except to obtain an image, when electron applicators are fitted;

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

(6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(O) Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

(2) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

(3) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

(4) For equipment manufactured after July 9, 1999, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

(P) Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(2) The mode of operation shall be displayed at the treatment control panel;

(3) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(5) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1999:

(a) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10° of rotation or one cm of linear motion differs by more than 20% from the selected value;

(b) Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5% from the dose monitor unit value selected;

(c) An interlock shall be provided to prevent motion of more than 5° or one cm beyond the selected limits during moving beam radiation therapy;

(d) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

(e) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position

sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

(6) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 105 CMR 120.437(J); and

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(7) For equipment manufactured after July 9, 1999, an interlock system shall be provided to terminate irradiation if movement:

(a) Occurs during stationary beam radiation therapy; or

(b) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

(Q) Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV. In addition to shielding adequate to meet requirements of 105 CMR 120.439, the following design requirements are made:

(1) Protective Barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

(2) Control Panel. In addition to other requirements specified in 105 CMR 120.430, the control panel shall also:

(a) Be located outside the treatment room;

(b) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(c) Provide an indication of whether radiation is being produced; and

(d) Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine;

(3) Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

(4) Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

(5) Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

(6) Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

(7) Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 105 CMR 120.221(A). and 120.221(B), interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

(8) Sliding Shielding Doors. Registrants with treatment rooms which utilize sliding shielding doors or other doors so massive that they may become jammed in the case of catastrophe will have in place an emergency plan to address such failure. In addition:

(a) Each door to a treatment room installed after July 9, 1999 will be equipped with an independent means of opening operable by a single able individual;

(b) Each sliding door installed after July 91, 1999 will be equipped with an electronic sensor which will immediately stop and disable the door closer (or reverse its motion) in the event of an imminent collision between the door and a person or object in its path.

(9) Emergency Cutoff Switches. At least three emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 105 CMR 120.437(K). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

(10) Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

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(11) Surveys for Residual Radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

(R) Radiation Therapy Physicist Support.

(1) The services of a Radiation Therapy Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiation Therapy Physicist shall be responsible for:

(a) Full calibration(s) required by 105 CMR 120.437(T) and protection surveys required by 105 CMR 120.434(A);

(b) Supervision and review of dosimetry;

(c) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

(d) Quality assurance, including quality assurance check review required by 105 CMR 120.437(U)(5);

(e) Consultation with the authorized user in treatment planning, as needed; and

(f) Perform calculations/assessments regarding misadministrations.

(2) Radiation therapy facilities shall have a minimum of one half-time radiological physicist available on a regular, on going, basis. In addition, radiation therapy facilities will have a minimum of one full time equivalent radiological physicist for every 500 total patients per year.

(3) If the Radiation Therapy Physicist is not a full-time employee of the registrant, the operating procedures required by 105 CMR 120.437(S) shall also specifically address how the Radiation Therapy Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Radiation Therapy Physicist can be contacted.

(S) Operating Procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 105 CMR 120.434(A), 120.437(T) and 120.437(U). have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

(T) Acceptance Testing, Commissioning and Full Calibration Measurements.

(1) Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to 105 CMR 120.437 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist.

(2) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: ~~Report of~~ AAPM Report No. 47", prepared by Radiation Therapy Task Group 45" and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

(3) Full calibration shall include measurement of all applicable parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46," prepared by ~~-~~Committee Task Group 40" and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: ~~Report of~~ AAPM Report No. 47" prepared by Radiation Therapy Task Group 45". Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.

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(4) The Radiation Therapy Physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

(a) Whenever quality assurance check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and,

(b) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 105 CMR 120.437(T)(4)(a).

(5) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

(U) Periodic Quality Assurance Checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 105 CMR 120.437 at intervals not to exceed those specified in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46," prepared by ~~of~~ AAPM Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations;

(2) To satisfy the requirement of 105 CMR 120.437(U)(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "Comprehensive QA for Radiation Oncology: AAPM Report No. 46 ~~of AAPM~~ prepared by Radiation Therapy Committee Task Group 40" or the most current AAPM published recommendations. Representative sampling shall include all applicable referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been inter-compared within the previous 12 months with the dosimetry system described in 105 CMR 120.434(C)(1) to make the periodic quality assurance checks required in 105 CMR 120.437(U)(2);

(4) The registrant shall perform periodic quality assurance checks required by 105 CMR 120.437(U)(1) in accordance with procedures established by the Radiation Therapy Physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(a) The authorized user and Radiation Therapy Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Radiation Therapy Physicist has determined that all parameters are within their acceptable tolerances;

(b) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or Radiation Therapy Physicist within three treatment days; and

(c) The Radiation Therapy Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(6) Therapeutic radiation machines subject to 105 CMR 120.437 shall have applicable safety quality assurance checks listed in the most currently published recommendations of reports of the AAPM Radiation Therapy Committee Task Group 40 at intervals not to exceed the frequencies recommended therein;

(7) To satisfy the requirement of 105 CMR 120.437(U)(6), safety quality assurance checks shall ensure proper operation of:

(a) Electrical interlocks at each external beam radiation therapy room entrance;
(b) Proper operation of the "BEAM-ON", interrupt and termination switches;
(c) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
(d) Viewing systems;
(e) Electrically operated treatment room door(s) from inside and outside the treatment room;

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(f) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(8) The registrant shall promptly repair any system identified in 105 CMR 120.437(U)(7) that is not operating properly; and

(9) The registrant shall maintain a record of each quality assurance check required by 105 CMR 120.437(U)(1) and (U)(7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

120.438: Calibration of Survey Instruments

(A) The registrant shall ensure that the survey instruments used to show compliance with 105 CMR 120.430 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

(B) To satisfy the requirements of 105 CMR 120.438(A), the registrant shall:

(1) Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately ⅓ and ⅔ of full-scale; and

(3) Calibrate automatically ranging digital display survey instruments at no less than one point on each decade and at no less than two points on one of these decades. These points should be at approximately ⅓ and ⅔ of the decade.

(C) To satisfy the requirements of 105 CMR 120.438(B), the registrant shall:

(1) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10%; and,

(2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20% if a correction factor or graph is conspicuously attached to the instrument.

(D) The registrant shall retain a record of each calibration required in 105 CMR 120.438(A) for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

(E) The registrant may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by 105 CMR 120.438(D) shall be maintained by the registrant.

120.439: Shielding and Safety Design Requirements

(A) Each therapeutic radiation machine subject to 105 CMR 120.436 or 120.437 shall be provided with such primary and/or

secondary barriers as are necessary to ensure compliance with 105 CMR 120.211 and 120.221.

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(B) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for Agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in 105 CMR 120.440: *Appendix A*.

120.440: Appendix A: Information on Radiation Shielding Required for Plan Reviews

I. ALL THERAPEUTIC RADIATION MACHINES

A. Basic facility information including: name, telephone number and Agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. THERAPEUTIC RADIATION MACHINES UP TO 150 kV (PHOTONS ONLY)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output, [expressed in gray (rad) or air kerma at one meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale [0.25 inch = one foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 105 CMR 120.211.

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each

physical condition [ie: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)] and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, please also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

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III. THERAPEUTIC RADIATION MACHINES OVER 150 kV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced [*ie*: photon, electron]. The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output [expressed in gray (rad) at one meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = one foot is typical], type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [*ie*: room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [ie: primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility.

(1) If commercial software is used to generate shielding require- ments, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. NEUTRON SHIELDING

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [ie: restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility.

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(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/ revision date.

(2) If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. REFERENCES

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

D. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).